and Research (CBER) and the Director, Office of Compliance and Biologics Quality, CBER.

(2) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER) and the Director and Deputy Director, Office of Compliance, CDER.

(g) These officials may not further redelegate these authorities.

§ 5.801 Export of unapproved drugs.

(a) The following officials are authorized, under section 802(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382(b)(2) and (b)(3)), to grant or deny petitions to export unapproved new drugs and biological products and to issue notices of receipt of such petitions for human drugs assigned to their respective organizations:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(2) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(3) The Director, the Deputy Director, and the Directors, Office Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(4) The Director and Deputy Director, Office of Compliance, CDER.

(b) The following officials are authorized, under section 802(e) of the act (21 U.S.C. 382(e)), to approve or disapprove an application to export a drug (including a biological product) to be used in the prevention or treatment of a tropical disease or another disease as described in section 802(e) for human drugs assigned to their respective organizations:

(1) The Director and Deputy Directors, CBER.

(2) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER.

(4) The Director and Deputy Director, Office of Compliance, CDER.

(c) The following officials are authorized, under section 351(h) of the Public Health Service Act (42 U.S.C. 262(h)), to approve or disapprove an application to export a partially processed biological product:

(1) The Director and Deputy Directors, CBER.

(2) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(d) These officials may not further redelegate these authorities.

§ 5.802 Manufacturer's resident import agents.

The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to reject manufacturer's designation of import agents under § 1005.25(b) of this chapter. These officials may not further redelegate this authority.

Subpart K—Orphan Products; Redelegations of Authority

§ 5.900 Orphan products.

(a) The Director, Office of Orphan Products Development (OPD), Office of the Senior Associate Commissioner (OSAC), Office of the Commissioner (OC), is authorized to issue notices, and amendments thereto, inviting sponsorship for orphan products (human and animal drugs, biological products, and medical devices) and submission of:

(1) Notices of claimed investigational exemption for a new drug or new drug applications;

(2) Notices of claimed investigational exemption for a new animal drug or new animal drug applications;

(3) Applications for biologics licenses for biological products; or

(4) Applications for an investigational device exemption or premarket approval applications for medical devices, as appropriate.

(b) The Director, OPD, OSAC, OC, is authorized:

(1) To determine whether there is reason to believe that a drug is a drug for a disease or condition that is rare in the United States under section 525(a) of the Federal Food, Drug, and

Cosmetic Act (the act) (21 U.S.C. 360aa(a)) and to designate such drug as a drug for a rare disease or condition under section 526(a) of the act (21 U.S.C. 360bb(a)).

(2) To issue holders of approved applications or licenses notice and opportunity for the submission of views under section 527(b)(1) of the act (921 U.S.C. 360cc(b)(1)).

(3) To encourage sponsors of an investigational new drug for a rare disease or condition to design protocols for clinical investigations to permit the addition to the investigation of persons with the disease or condition under section 528 of the act (21 U.S.C. 360dd).

(c) The following officials are authorized to provide sponsors, under section 525(a) of the act (21 U.S.C. 360aa(a)), with recommendations for nonclinical or clinical investigations believed to be necessary for a drug for a rare disease or condition to be approved or licensed:

(1) For drugs under their jurisdiction:

(i) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) For biological products under their jurisdiction:

(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), Office of Therapeutics Research and Review (OTRR), CBER.

(iii) The Directors and Deputy Directors of the Divisions in OBRR, OVRR, and OTRR, CBER.

(d) These officials may not further redelegate these authorities.

Subpart L—Mammography Facilities; Redelegations of Authority

§ 5.1000 Authority to ensure that mammography facilities meet quality standards.

(a) The following officials are authorized to ensure mammography facilities obtain certificates under section 354(b) of the Public Health Service Act (the PHS Act) (42 U.S.C. 263b(b)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Health and Industry Programs (OHIP), CDRH.

(3) The Director and Deputy Director, Division of Mammography Quality and Radiation Programs (DMQRP), OHIP, CDRH.

(b) The following officials are authorized to issue, renew and extend certificates to mammography facilities under section 354(c) of the PHS Act (42 U.S.C. 263b(c)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(c) The following officials are authorized to accept an application for a certificate under section 354(d)(1) of the PHS Act (42 U.S.C. 263b(d)(1)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(d) The following officials are authorized to approve accreditation bodies to accredit mammography facilities under section 354(e)(1)(A) of the PHS Act (42 U.S.C. 263b(e)(1)(A)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.